K131529

510(K) SUMMARY

SEP 24 2013

This 510(k) summary of safety and effectiveness for **Shengguang Manual Wheelchair** is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Table 1 General Information

Applicant:	Pingdingshan Shenxing Healthcare Technology Co., Ltd.
Address:	Xinxing Road South of industrial Park, Lushan County, Pingdingshan City Henan P.R. China
Contact Person:	Wang Qing
Telephone:	(86 0375)- 5620005
Email:	kenwqing@gmail.com
Date of Preparation:	Aug. 28, 2013
Device Name:	SHENGGUANG MANUAL WHEELCHAIR
Classification Name:	Manual Wheelchair
Device Class:	Class I
Regulation Number	890.3850
Product Code:	IOR
Classification Panel	Physical Medicine
Type of submission	Traditional 510K

Intended use:

The **Shengguang Manual Wheelchair** is intended for medical purposes to provide mobility to persons restricted to a seated position.

Indications for Use:

The **Shengguang Manual Wheelchair** is intended for medical purposes to provide mobility to persons restricted to a seated position. **Shengguang Manual Wheelchair** is not designed, sold, or intended for use except as indicated.

Device Description

The Shengguang Manual Wheelchair is an indoor/outdoor wheelchair that has a base with four-wheels with a seat. The device can be disassembled for transport and it is foldable easily. Both the back and seat upholstery material is the same resistance-ignitability fabric.

All device functions, scientific concepts, significant physical and performance characteristics (i.e. device design, materials, physical properties, etc.) are identical to the design and manufacture described in Predicate Devices.

Predicate Devices:
- Universal Wheelchair by Graham-Field Health Products, Inc. (Formerly Everest & Jennings), 510(k) # K930411.
- 7000 Series Lightweight Wheelchairs by Nova Ortho-Med, Inc., 510(k) # K061273.

Substantial Equivalence Discussion
Shenxing Healthcare Technology Co. believes that its **Shengguang Manual Wheelchair** is substantially equivalent to the Predicate Devices for the following reasons.

The **Shengguang Manual Wheelchair** has the same indication as the predicate device that it is intended for medical purposes to provide mobility to persons restricted to a seated position.

There are no significant differences between the specifications, functions and performance of Shengguang Manual Wheelchair and legally marketed predicate devices to which it is claimed to be substantially equivalent.

Summary of Substantial Equivalence Comparison

Table 2: Descriptive Comparison of Shengguang Manual Wheelchair to Predict Devices

ITEMS	SUBJECT DEVICE				PREDICATE DEVICE	PREDICATE DEVICE
BRAND NAME	SHENG GUANG	SHENG GUANG	SHENG GUANG	SHENG GUANG	Everest&Jennings	Nova
MANUFACTURER	Pingdingshan Shenxing Healthcare Technology Co., Ltd				Graham-Field Health Products	Nova Ortho-med Inc.
MODEL NO	SG-LY-001001 (Fixed armrest)	SG-LY-001016 (detachable short armrest)	SG-LY-001017	SG-LY-001018	Metro IC4 (3D020120) (Universal Wheelchair)	Nova 7160L/7180L
510K NO					K930411	K061273
INTENDED USE	Same	Same	Same	Same	The device is intended for medical	To provide mobility to adult persons with

						purposes to provide mobility to persons restricted to a seated position	limited mobility or adult persons limited to a seated position. (Over-The-Counter Use)
frame	Primary Material	Same	Same	Same	Same	Welded steel tube	Welded steel tube
	width	16"/18" (406mm/457mm/)	Same	Same	Same	16"/18"/20" (406mm/457mm/508mm)	16"/18"/20" (406mm/457mm/508mm)
	Cross brace	Same	Same	Same	Same	Yes	Yes
	Depth	895mm	895mm	895mm	Same	915mm	915mm
	Seat	Same	Same	Same	Same	Width:16"/18"/20" (406mm/457mm/508mm)	Width:16"/18"/20" (406mm/457mm/508mm)
		Same	Same	Same	Same	Depth 16"(406mm)	Depth 16"(406mm)
	Backrest height	Fixed	Fixed	Fixed	Same	adjustable	adjustable
	Reclining backrest	Same	Same	Same	Same	Fixed	Fixed
	Seat sling	Same	Same	Same	Same	Padded nylon	Padded nylon
	Frame colors	Same	Same	Same	Same	Black	Black
Armrest	Arm pad	Same	Same	Same	Same	Padded	Padded
	Flip back	Fixed	Detachable	Detachable	Same	Flip back	Flip back
	Height-adjustable	Same	Same	Same	Same	No	No
HANGERS	Swing-away	Same	Same	Same	Same	Yes	Yes
	Elevating leg rest	Same	Same	Same	Same	Yes	Yes
	Articulating leg rest	Same	Same	Same	Same	No	No
	Footplate style	Same	Same	Same	Same	PA	PA
	Heel loop	Same	Same	Same	Same	No	No
	Footrest angle	Same	Same	Same	Same	20°	20°
REAR	Offset axle	Same	Same	Same	Same	No	No

AXLE	Quick-release axle	Same	Same	Same	Same	No	No
	Whorl	Same	Same	Same	Same	Yes	Yes
REAR WHEEL	Size	Same	Same	Same	Same	24" Solid nylon	24" Solid Nylon
	Tire type						
	Handrim material						
CASTERS	Size	Same	Same	Same	Same		8" Solid
	Tire type						
WHEEL LOCK		Same	Same	Same	Same	Manual	Manual
Upholstery Material		PVC (Same as GF Vista)	PVC (Same as GF Vista)	Same	Same	.Nylon	Nylon
WEIGHT CAPACITY		250lbs	250lbs	Same	Same	300lbs/136kg	300lbs/136kg
WEIGHT OF CHAIR		17.3kg (38lb)	18.6kg (41lb)	17.3kg (38lb)	Same	15.5kg(34lb)	15.5kg(34lb)
WARRANTY		Same	Same	Same	Same	5 years on frame	5 years on frame
OPTIONAL ACCESSORIES	Anti-tipper	No	No	No	Same	Yes	Yes

The **Shengguang Manual Wheelchair** and the predicate devices employ the same technology and are similar in design, dimensions and other technological features. As seen in Table 2, the only differences in features between the **Shengguang Manual Wheelchair** and the predicate Devices are small differences in the weight of the wheelchair, style of the backrest height and armrest. These differences do not affect the safety and effectiveness of the **Shengguang Manual Wheelchair** compared to the predicate device.

Technological/Safety Characteristics and Performance Testing

The **Shengguang Manual Wheelchair**'s technological and safety characteristics are identical to those described in the Predicate Devices.

Non-clinical testing has been performed on the Shengguang Manual Wheelchair and the results demonstrate compliance with the following standards:

ANSI/RESNA WC-1:2009 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 1 Determination of static stability

ANSI/RESNA WC-1:2009 Section3: Determination of effectiveness of brakes

ANSI/RESNA WC-1:2009 Section 5: Determination of dimensions, mass and maneuvering space

ANSI/RESNA WC-1:2009 Section 7: Method of Measurement of Seating and Wheel Dimensions

ANSI/RESNA WC-1:2009 Section 8: Requirements and test methods for static, impact and fatigue strengths

ANSI/RESNA WC-1:2009 Section 11: Test dummies

ANSI/RESNA WC-1:2009 Section 13: Determination of coefficient of friction of test surfaces

ANSI/RESNA WC-1:2009 Section 15: Requirements for information disclosure, documentation and labeling

The upholstery material for the SG-LY-001001/ SG-LY-001016 and SG-LY-001017/SG-LY-001018 series is the same as those used for the Graham Field Vista model and the Graham Field Metro IC4 model, respectively. It was tested in accordance with the California Technical Bulletin 117 Section E Part 1 and was shown to be Class 1 – normal flammability.

The foam material for the seat cushion was tested for flammability in accordance with the California Technical Bulletin 117 Section A Part 1 and Section D Part 2, and was shown to meet the performance standards.

Biocompatibility

The patient contacting components of the **Shengguang Manual Wheelchair** use the same materials, have the same chemical composition, and are manufactured using the same process by the same suppliers, as those of the Predicate Devices. Therefore, the Shengguang Manual Wheelchair meets the biocompatibility requirements in accordance with FDA Guidance G95-1. The comparison is shown in Table 3a and Table 3b.

Table 3a. Comparison with Predicate Device Parts:

Model	Parts	Material	Comparison Device	510(k) NO.
Shengguang Manual Wheelchair Series	Handgrip	PVC	YUYUE K2 Wheelchair	K120526
	Armrest shell	ABS	YUYUE K2 Wheelchair	K120526
	Handrim	Nylon	YUYUE K2 Wheelchair	K120526
	Brake handle	Rubber	YUYUE K2	K120526

			Wheelchair	

Table 3b. Comparison with Predicate Device Parts:

Model	Parts	Material	Comparison Device	510(k) NO.
Shengguang Manual Wheelchair Series	Upholstery of seat and back	Oxford cloth, PVC	YUYUE K2, K4 Wheelchair	K120526
			JUMAO MANUAL WHEELCHAIR	K082784

Conclusion:

The data submitted in this 510(K) Premarket Notification supports the finding that this device is substantially equivalent with respect to the intended use, technology, functionality, and safety features to the legally marketed Predicate Devices. Therefore, we believe that this device meets the requirement for a "Substantial Equivalence" decision in accordance with the 510(K) guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 24, 2013

Pingdingshan Shenxing Healthcare Technology Co., LTD
c/o Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K131529
Trade/Device Name: Shengguang Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: September 11, 2013
Received: September 12, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131529

Device Name: Shengguang Manual Wheelchair

Indications For Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S